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Joseph R. Baker, APC
Gavrilovich, Dodd & Lindsey LLP
4660 La Jolla Village Drive, Suite 750
San Diego, CA 92122

EXAMINER	
WANG, CHANG YU	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,619	MARTIN, PAUL TAYLOR	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/8/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-26* is/are pending in the application.

4a) Of the above claim(s) *13-18 and 24-26* is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 9* is/are allowed.

6)☒ Claim(s) *5-8,10-12 and 19-23* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Election/Restrictions

1. Applicant's election without traverse of Group V (claims 1-12 and 19-23 that are directed to SEQ ID NO:5) and integer 1-20 in the reply filed on 6/8/09 is acknowledged.

Claims 1-3 and 5-26 are pending. Claim 4 is canceled. Claims 13-18 and 24-26 are withdrawn without traverse (filed on 6/8/09) from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/8/09. Upon reconsideration, the species election on integer is withdrawn.

2. Claims 1-3, 5-12 and 19-23 are under examination with respect to SEQ ID NO:5 in this office action.

Claim Objections

3. Claims 3 and 5-8 are objected to because of the following informalities: Claim 3 is objected to because the claim recites "the cysteine are intramolecularly cross linked via a disulfide bond", which is grammatically incorrect. It should be "the cysteine residues are intramolecularly cross-linked via a disulfide bond". In addition, claims 5-8 are objected to because the claims recite "the isolated polypeptide of claims 1……from 1 to 15 (1 to 10, 1 to 5 or 1 to 3) amino acid…...", which is grammatically incorrect. It

should be "the isolated polypeptide of claim 1… 1 to 15 (1 to 10, 1 to 5 or 1 to3) amino acids.....". Appropriate correction is required.

4. Claim 18 is objected to because of the following informalities: the status of the claim 18 is incorrect because the claim is withdrawn from consideration. Appropriate correction is required.

See MPEP 714 & 37 CFR 1.121.
"In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered)."

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8, 11 and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 are indefinite because the claims recite "from 1 to 15 (1 to 10, 1 to 5 or 1-3) amino acid at the N- or C-terminus of the polypeptide comprising SEQ ID NO:5. The recitation "from 1 to 15 (1 to 10, 1 to 5 or 1-3) amino acid at the N- or C-terminus is not clear. It is not clear whether the recitation of "1 to 15 amino acid" in claim 5 means "the residue number that has 1 to 15 amino acids.." or whether it means "the amino acid residue position at 1 to 15 amino acids at the N-terminus or C-terminus…". The same issue is also found in the recitation of "1 to 10, 1 to 5 or 1 to 3" in claims 6-8.

In addition, claim 11 is indefinite because the claim recites both a narrow limitation (i.e. consisting of SEQ ID NO: 4 or 5 as in claims 2 and 9) and a boarder limitation (i.e. further comprising a therapeutic or diagnostic compound conjugated to the polypeptide), which renders the claim indefinite. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 11 recites the broad recitation “further comprising a therapeutic or diagnostic compound conjugated to the polypeptide”, and the claim also recites “consisting of SEQ ID NO:4 or 5”, which is the narrower statement of the range/limitation.

Claim 11 depends from claims 2 and 9 and also recites “further comprising a therapeutic or diagnostic compound conjugated to the polypeptide”. However, claim 2 is directed to an isolated polypeptide consisting of the amino acid sequence of SEQID

NO:5, which is a closed limitation that only contains the amino acid sequence of SEQ ID NO:5. In addition, claim 9 is directed to an isolated polypeptide comprising or consisting of the amino acid sequence of SEQ ID NO:4. The limitation of “consisting of the amino acid sequence of SEQ ID NO:4” is also a closed limitation that only contains the amino acid sequence of SEQ ID NO:4.

Further, claims 21 and 22 are indefinite because claim 21 recites "a sufficient portion" and claim 22 recites “less toxic”. The term "a sufficient portion" in claim 21 and the term ”less toxic” in claim 22 are a relative term, which renders the claims indefinite. The terms “a sufficient portion " and “less toxic” are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant fails to set forth the metes and bounds of what is encompassed within the definition of “a sufficient portion” and what is encompassed within the definition of "less toxic". Since the metes and bounds are unknown, a skilled artisan can not envision what would be "a sufficient portion" and what degree of toxicity would be considered as less toxic as recited in the claims. Thus, the claims are indefinite.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8, 10-11 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising or consisting of the amino acid sequence of SEQ ID NO:4 or 5, does not reasonably provide enablement for an isolated polypeptide comprising the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5 and further comprising undefined amino acid sequences or undefined therapeutic/diagnostic compounds, or a hybrid molecule or a composition comprising the claimed polypeptide and undefined scaffold molecules or reagents for treating or diagnosing Alzheimer's disease as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

"There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'. These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)". See MPEP § 2164.01.

Claims 5-8 are drawn to an isolated polypeptide comprising the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5 and further

comprising from 1 to 15, 1 to 10, 1 to 5 or 1 to 3 amino acid at the N- or C-terminus of the polypeptide comprising SEQ ID NO:5. Claims 10-12 and 19-23 are drawn to an isolated polypeptide and a composition comprising the amino acid sequence of SEQ ID NO: 4 or 5 and further comprising a therapeutic or diagnostic compound, and a hybrid molecule comprising the amino acid sequence of SEQ ID NO: 4 or 5 and further comprising a scaffold molecule comprising a therapeutic or diagnostic reagent for treating or diagnosing Alzheimer's disease. The claims encompass undefined amino acid sequences or undefined therapeutic/diagnostic compound, a hybrid molecule or a composition comprising the claimed polypeptide and undefined scaffold molecule or reagents. In addition, the claims encompass the use of the claimed polypeptide comprising undefined sequences and undefined molecules to treat or diagnose Alzheimer's disease.

The instant invention is based on a finding that an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:4 or 5 can bind to Abeta 1-40 polymeric peptides but not monomeric Abeta 1-40 peptides. The instant specification also shows that the polypeptide comprising the amino acid sequence of SEQ ID NO:4 or 5 conjugated to biotin or fused to thioredoxin can be used to detect the amyloid plaques composed of Abeta 1-40 peptides on Alzheimer's brain sections.

Based on the specification and the prior art, Applicant is enabled for an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:4 or 5 for binding to Amyloid plaques formed by Abeta 1-40 peptide aggregates. In addition, Applicant is enabled for the use of the claimed polypeptide comprising the amino acid sequence of

SEQ ID NO:4 or 5 that is conjugated to biotin or other defined proteins or molecules known in the art for detection and diagnosis purposes. However, the claims are not limited to the molecules as set forth above and are not limited to the use as set forth above.

Claims 5-8 are directed to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 5 and also comprising undefined sequences of "from 1 to 15, 1 to 10, 1 to 5 or 1 to 3 amino acid at the N- or C-terminus of the polypeptide comprising SEQ ID NO:5". The specification provides insufficient guidance to enable a skilled artisan to practice the full scope of the claimed invention without undue experimentation. The claims recite "further comprising undefined sequences of "from 1 to 15, 1 to 10, 1 to 5 or 1 to 3 amino acid at the N- or C-terminus of the polypeptide comprising SEQ ID NO:5". It is unclear what these additional undefined amino acid sequences are. The specification fails to teach what specific common structures and sequences are required for the claimed polypeptide to bind to Abeta1-40 peptide aggregates. The specification also fails to teach what amino acid sequences can or cannot be changed in the claimed polypeptide to preserve the binding property of SEQ ID NO:4 or 5 to Abeta 1-40 peptide aggregates. Thus, it is unpredictable whether these additional sequences would alter the binding property of the SEQ ID NO:5 to Abeta 1-40 aggregates. It is unpredictable whether other polypeptides comprising additional undefined amino acid sequences in different lengths and at different positions within the undefined N- or C-terminus of SEQ ID NO:5 can be used to bind to Abeta 1-40 aggregates because an amino acid modification on a molecule can abolish the binding

activity of the molecule. For example, a substitution of lysine residue by glutamic acid at position 118 of acidic fibroblast growth factor results in a substantial loss of its biological activity including the binding ability to heparin and its receptor (Burgess et al. J of Cell Bio. 1990, 111:2129-2138). Although many amino acid substitutions are possible in any given protein, the position of where such amino acid substitutions can be made is critical for maintaining the function of a protein; i.e. only certain positions can tolerate conservative substitutions without changing the relationship of three dimensional structure and function of the protein (col 2, p. 1306, Bowie et al. Science, 1990, 247:1306-1310). In addition to a core determinant sequence, the protein-protein interaction also relies on the flanking or noncontiguous residues (see p. 445 the second column, first paragraph, Pawson et al. 2003, Science 300:445-452). The optimal binding motif for a domain is not necessarily suitable for physiological or in vivo interaction. The predictive data always need to be validated by actual analyses in cells (see p. 445, the third column, second paragraph, Pawson et al. 2003, Science 300:445-452). The instant specification fails to teach what amino acid sequences can or cannot be included/changed in the claimed polypeptide in order to preserve the binding activity of SEQ ID NO:4 or 5 to Abeta 1-40 aggregates.

In addition, claims 10 and 19 recite Abeta peptides. As shown in the specification on p. 35-36, only Abeta 1-40 peptide aggregates can be bound by the claimed polypeptides of SEQ ID NO:4 and 5. The recitation of Abeta peptide in claims 10 and 19 encompasses all different forms of Abeta peptides. However, neither the specification nor the prior art shows that all forms of Abeta peptides can be bound by the claimed

polypeptides. Neither the specification nor the prior art teaches the structural and functional relationship between Abeta 1-40 aggregates and other forms of Abeta peptides that can be bound by SEQ ID NO:4 or 5. Thus, it is unpredictable whether other forms of Abeta peptide can be bound by the claimed polypeptides.

Furthermore, claims 11-12 and 19-23 are directed to the claimed polypeptide comprising the claimed polypeptide and a therapeutic or diagnostic compound or a hybrid molecule comprising the claimed polypeptide and a scaffold molecule comprising a diagnostic or therapeutic reagent wherein the reagent comprises a polypeptide, small molecule or compound. Although the specification describes antioxidant reagents or anti-idiotype antibodies as possible therapeutic reagents on p.22-24 and figure 7, the specification fails to teach what specific therapeutic reagents, neuroprotective agents, antioxidant reagents or anti-idiotype antibodies are and whether they are can be used to effectively to treat Alzheimer's disease or other treatment.

While the skill level in the art is high, the level of predictability is low because the specification fails to provide guidance or working examples as to enable a skilled artisan how to make and use the claimed polypeptides, the claimed composition or the claimed hybrid molecules in vivo to treat AD or for other treatment. It is known in the art that Applicant's invention is on the hypothesis that the therapeutic reagents are known and can be used to treat AD. However, this is not the case because the specification provides insufficient guidance to enable a skilled artisan how to make and use the claimed hybrid molecules or polypeptides comprising therapeutic agents comprising

undefined polypeptides, small molecules or compounds. It appears that Applicant provides a single finding, and then presents an invitation to others to determine what other therapeutic reagents, scaffold molecules are and what a sufficient portion of a protein selected from the group consisting of antibodies, enzymes, chromogenic proteins, fluorescent proteins and fragments thereof is. The specification fails to teach what specific common structures or amino acid sequences are required by the claimed therapeutic reagents, scaffold molecules are and what a sufficient portion of a protein selected from the group consisting of antibodies, enzymes, chromogenic proteins, fluorescent proteins and fragments thereof is. The instant specification fails to disclose how the claimed polypeptides compositions or hybrid molecules can be used for treatment. In the absence of this guidance, a practitioner would have to resort to a substantial amount of undue experimentation involving in deciphering what an unknown therapeutic reagent, scaffold molecule, an unknown portion of a protein, or a unknown neuroprotective agent is and whether these unknown molecules or regents can be used for treatment. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not follow the guidance presented therein and practice the claimed method without first making a substantial inventive contribution. Therefore, in view of the breadth of the claims, the lack of working example and guidance in the specification, the unpredictability of inventions, and the current status of the prior art, undue experimentation would be required by a skilled artisan to perform in order to practice the claimed invention as it pertains to the claimed polypeptide, the claimed composition and the claimed hybrid molecule.

Claim Rejections - 35 USC § 112

7. Claims 5-8, 10-11 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 5-8 are drawn to an isolated polypeptide comprising the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5 and further

comprising from 1 to 15, 1 to 10, 1 to 5 or 1 to 3 amino acid at the N- or C-terminus of the polypeptide comprising SEQ ID NO:5. Claims 10-12 and 19-23 are drawn to an isolated polypeptide and a composition comprising the amino acid sequence of SEQ ID NO: 4 or 5 and further comprising a therapeutic or diagnostic compound, and a hybrid molecule comprising the amino acid sequence of SEQ ID NO: 4 or 5 and further comprising a scaffold molecule comprising a therapeutic or diagnostic reagent for treating or diagnosing Alzheimer's disease. Claims 5-8 encompass a genus of polypeptides comprising a genus of undefined amino acid sequences 1-15, 1-10, 1-5 and 1-3 amino acid at the N- or C-terminus of SEQ ID NO:5. Claims 10-12 and 19-23 encompass a genus of Abeta peptides, a genus of undefined therapeutic compounds and a genus of hybrid molecules comprising a genus of scaffold molecules comprising a genus of diagnostic or therapeutic reagents that comprises a genus of polypeptides, small molecules or compounds. Claim 21 also encompasses a genus of a sufficient protein selected from the group consisting of antibodies, enzymes, chromogenic proteins, fluorescent proteins and fragments thereof. Claim 22 also encompass a genus of neuroprotective agents that render amyloid plaques less toxic or inhibit plaque formation. The specification only describes SEQ ID NO:4 or 5 that binds to Abeta 1-40 aggregates and describes polypeptides of SEQ ID NO:4 or 5 conjugated to biotin or Thioredotoxin. However, the claims are not limited to the polypeptides and reagents as set forth above.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand

what Applicant is in possession of and what Applicant is claiming. From the specification, it is clear that Applicant is in possession of isolated polypeptides comprising or consisting of SEQ ID NOs:4 and 5. In addition, Applicant is also predictable in possession of the claimed polypeptides conjugated to defined proteins or compounds that are known in the art for detection or diagnosis purposes. However, Applicant is not in possession of the claimed polypeptides comprising additional undefined sequences at undefined positions in SEQ ID NO:5 as recited in claims 5-8. Applicant is also not in possession of all forms of Abeta peptides for the claimed polypeptides to bind as recited in claims 10 and 19. In addition, Applicant is not in possession of structurally and functionally undefined therapeutic reagents or hybrid molecules comprising structurally and functionally undefined scaffold molecules or therapeutic reagents as recited in claims 11 and 19-23. Furthermore, Applicant is not in possession of a structurally and functionally undefined portion of a protein as in claim 21 or neuroprotective agents that render amyloid plaques less toxic or inhibit plaque formation as in claim 22.

Although the specification describes several possible therapeutic reagents on p. 22-24, the specification fails to define what these possible therapeutic reagents or scaffold molecules are. Thus, Applicant is not in possession of the claimed polypeptide comprising undefined therapeutic reagents or neuroprotective agent that render amyloid plaques less toxic or inhibit plaque formation for treating AD or other treatment. The specification only describes SEQ ID NOs:4 and 5. There is no identification of any particular portion of the structure that must be conserved. The instant specification fails

to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polypeptides as in claims 5-8, the claimed genus of therapeutic reagents, the claimed genus of hybrid molecules, the claimed genus of scaffold molecules, the claimed genus of sufficient portion of a protein selected from the group consisting of antibodies, enzymes, chromogenic proteins, fluorescent proteins and the claimed fragments thereof, and the claimed genus of neuroprotective agents that render amyloid plaques less toxic or inhibits plaque formation. There is no description of the conserved regions which are critical to the function of the claimed genera. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure of the claimed polypeptide of claims 5-8 to the function of SEQ ID NOs: 4 and 5. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure of the claimed genera. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to identify what other polypeptides as in claims 5-8, therapeutic reagents, hybrid molecules and scaffold molecules might be and what a sufficient portion of a protein selected from the group consisting of antibodies, enzymes, chromogenic proteins, fluorescent proteins and the claimed fragments thereof, and neuroprotective agents might be. Since the common characteristics/features of other polypeptides and molecules are unknown, a skilled artisan cannot envision the functional correlations between the claimed genera and the claimed invention. Accordingly, in the absence of sufficient recitation of

distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of proteins.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, therapeutic reagents, hybrid molecules, neuroprotective agents and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claimed polypeptides, composition, and hybrid molecules have not met the written description provision of 35 U.S.C. §112, first paragraph. Applicant is

reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement. See MPEP § 2163.

Conclusion

Allowable Subject Matter

8. Claims 1-3 and 9 are free of prior art. However, claim 3 is objected to due to a grammatical error.

9. Claims 5-8, 10-12 and 19-23 are rejected.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chang-Yu Wang, Ph.D.
September 17, 2009

/Chang-Yu Wang/
Examiner, Art Unit 1649